Remarks/Arguments

The Office Action dated May 30, 2008 has been received and carefully studied. The Examiner objects to the newly submitted claims 18-24 as being directed to an invention that is independent or distinct from the originally claimed invention. By virtue of the accompanying amendment, these claims have been withdrawn.

The Examiner rejects claim 26 under 35 U.S.C. §112, second paragraph for failing to particularly point out and distinctly claim the invention. Specifically, the Examiner notes that the terms "supine" and "shunt" lack antecedent basis. By virtue of the accompanying amendment, claim 25 has been modified to provide proper antecedent basis for these terms.

The Examiner rejects claims 1, 2, 17, 25 and 26 under 35 U.S.C. §103(a) as being unpatentable over Madsen (U.S. Patent No. 6,383,160) in view of Cowan (U.S. Patent No. 6,585,677)

With respect to claim 1, the Examiner states that Madsen teaches a system for regulating the flow of CSF from the brain having 2 drainage paths, as claimed. Cowan, Jr. teaches a wireless transceiver in the form of transmitter 64 that is operable to receive and emit or transmit information with an external programmer external to the patient, and a embedded microprocessor within diagnostic unit 60 housed within the controller 24.

This rejection is respectfully traversed. Claim 1 recites "a multi mode drainage system, in which a first mode

is a low resistance substantially supine flow path and a second mode is a variable upright flow path, wherein the selection of said mode is controlled by said embedded microprocessor". Madsen does not disclose such a system.

The present claim requires that the "selection of said mode is controlled by said embedded microprocessor". Madsen does not have this feature. Madsen describes a system where fluid enters both pathways, however, it typically only passes through the path of less resistance. Madsen also describes an anti-siphon valve which has little or no resistance when the patient is recumbent, but has a "high fluid flow resistance that is greater than the fluid flow resistance of the high resistance valve 90". Column 6, lines 44-46. In other words, the resistance of the anti-siphon valve changes as a function of the patient's orientation. This change in resistance makes the high resistance path a more viable fluid path for CSF, and thus fluid starts passing through that pathway. However, the fluid is not directed from one path to another by a microprocessor as recited in the claims; rather fluid passes through the second path as a result of the automatic change in the resistance of the anti-siphon valve in response to the patient's change in orientation. This change in path is completely independent of the processor in the Madsen device, and would work in this manner even if Madsen did not have an embedded microprocessor to adjust the anti-siphon valve. Thus, Madsen does not disclose a system whereby the embedded microprocessor controls the flow of CSF based on the patient's inclination.

Furthermore, the Madsen device works in a fundamentally different way than the present invention. This device uses

the second drainage path only when "the cerebral spinal pressure increase[s] to dangerous levels while the patient is standing up". Column 6, lines 47-48. The first fluid path is the primary path and is adjustable via an actuator that "adjusts the adjustable barrier in the anti-siphon device in order to provide optimal treatment conditions for patient". Column 7, lines 15-17.

In other words, one fluid path is used when the patient is supine and this path has a cracking pressure that is adjustable based on the patient's orientation. The other fluid path has a much higher fixed cracking pressure and is only used when CSF pressure reaches a dangerous level.

In contrast, the present invention uses a low resistance path when the patient is substantially supine, and a variable resistance path when the patient is upright or nearly upright. In other words, both paths are used in normal operation, and it is the upright path which is adjustable. Madsen does not disclose or suggest this functionality as claimed. Thus, claim 1 is believed to be in condition for allowance.

The Examiner rejects claims 2 under 35 U.S.C. §103(a) as being unpatentable over Madsen and Cowan, Jr. et al. The Examiner states that Cowan teaches that the external computing device can automatically diagnose malfunction or infection and/or pass data to a doctor. The Examiner concludes that is would be obvious to one of ordinary skill in the art to modify the device of Cowan such that, once a diagnosis is made, the external programmer wirelessly

transmits data and commands to the controller to being a treatment process involving a proper amount of CSF drainage.

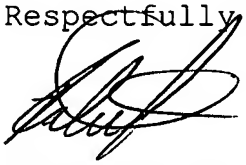
This rejection is respectfully traversed. The Examiner states that it would be obvious to one of ordinary skill in the art to modify the device so that the control transmits data and commands to the controller for treatment. However, it is believed that this modification is not obvious. In fact, Cowan contemplated the use of a transceiver in the disclosure, whereby data could be transmitted to the controller from an external device. Cowan discloses that the transceiver "would also accept uploaded information to shunt 20 from an external computing device. Such uploaded information can include, for example, reprogramming instructions for software programming used in the operation of in valve-gauge assembly 52 and/or diagnostic unit 60". (Column 7; lines 40-48). Cowan enumerated potential uses of the device if a transceiver were utilized. Clearly, if the use of the external programmer to command the controller were obvious, Cowan would have suggested such a usage in the disclosure. Rather, Cowan only suggests that incoming data can be used to reprogram the device, which is a different function than that recited in claim 2. Furthermore, by virtue of dependence of claim 2 on claim 1, claim 2 is believed to be allowable, since all of the recited elements of claim 1 are not disclosed.

Finally, the controller of the present invention, in conjunction with the external programmer, can execute diagnostic algorithms to determine a number of different parameters. These parameters include the distal flow resistance of the shunt in the supine mode from the pressure

sensor to the distal end of the shunt, the supine flow rate, cranial compliance, the proximal shunt flow resistance and regular monitoring of cerebrospinal fluid shunt flow resistance. This is not disclosed by Cowan.

Reconsideration and allowance are respectfully requested in view of the foregoing.

Respectfully submitted,



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